UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION This Document Relates to: All Cases	MDL No.: 1:13-md-2419-FDS
IN RE: NEW ENGLAND COMPOUNDING PHARMACY CASES This Document Relates to: All Cases	Master Docket No. 12-12052-FDS **AFFIDAVIT OF ELLIOT L. OLSEN**

STATE OF MINNESOTA)
)SS.
COUNTY OF HENNEPIN)

Elliot L. Olsen, being first duly sworn upon oath, states:

1. He is one of the attorneys of Party-In-Interest Tracy Maccoux with regard to the above-referenced matter.

2. Attached as Exhibit A is the Complaint in the matter entitled Maccoux v. Medical Advanced Pain Specialists, P.A.

3. Attached as Exhibit B is Defendant MAPS' Motion Pursuant to Rule 12 of the Minnesota Rules of Civil Procedure.

Dated:

PritzkerOlsen, P.A.

By: _____
Elliot L. Olsen (MN #203750)

Sworn and subscribed to before
me this 2nd day of May, 2013.

_____
Notary Public

SUSAN A. KAISER
Notary Public-Minnesota
My Commission Expires Jan 31, 2015

STATE OF MINNESOTA

COUNTY OF HENNEPIN

DISTRICT COURT

FOURTH JUDICIAL DISTRICT
PRODUCT LIABILITY

Traci M. Maccoux,

Plaintiff,

vs.

Medical Advanced Pain Specialists, P.A.,

Defendant.

Court File No.: 27-CV-13-4786
Judge: Ronald L. Abrams

COMPLAINT
(JURY DEMANDED)

Plaintiff, for her claims for relief, states and alleges that:

PARTIES & VENUE

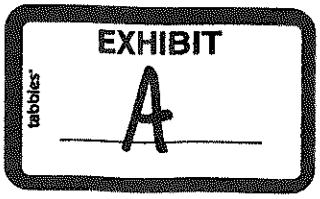
1. Plaintiff Traci M. Maccoux is an individual and resident of Brooklyn Park, Minnesota.

2. Defendant Medical Advanced Pain Specialists, P.A. ("MAPS") is a Minnesota corporation with its principal corporate office located at 2104 Northdale Boulevard NW, Suite 220, Coon Rapids, Minnesota 55433.

3. At all relevant times, MAPS operated a medical pain clinic at 9550 Upland Lane North, Suite 100, Maple Grove, Minnesota 55369.

4. The incident that is the subject matter of this litigation occurred during the summer of 2012 in Maple Grove, Minnesota when Plaintiff's healthcare provider, MAPS, injected her with contaminated medication produced by the New England Compounding Center ("NECC").

5. Accordingly, venue is properly placed in this Minnesota district court in and for Hennepin County, Minnesota.



FACTUAL BACKGROUND

Plaintiff's Medical Background

6. Plaintiff Traci M. Maccoux is an adult resident of Brooklyn Park, County of Hennepin, and the State of Minnesota.

7. In October 2001, at the age of eleven, Plaintiff was diagnosed with Complex Regional Pain Syndrome ("CRPS") Type 1, also known as Reflex Sympathetic Dystrophy. CRPS is a chronic pain condition that typically affects the extremities. CRPS originally affected Plaintiff's lower-left leg and in 2006 CRPS also affected her lower-right leg as well as both arms.

8. Plaintiff's treatment for CRPS has included, but has not been limited to, drug therapies, physical therapy, epidural injections, and implantation of spinal cord stimulators.

9. Plaintiff had spinal stimulators placed in her lower and upper spine in 2004 and 2005. Subsequently, the leads on the stimulators broke and Plaintiff underwent surgery on September 14, 2012, performed by Dr. Joseph H. Perra at Abbott Northwestern Hospital, to remove the spinal stimulators and placement of a silicone spacer at T11-L1 for treatment of her chronic pain. The silicone spacer was implanted as a space holder for future placement of spinal stimulators should they become ideal for her treatment again.

MAPS and Injection of Contaminated Steroid Product

10. Plaintiff first presented at MAPS Medical Pain Clinic in Maple Grove, Minnesota on, or approximately on, May 14, 2012 for bilateral leg pain and treatment for CRPS.

11. On July 31, 2012, Plaintiff presented at MAPS Clinic in Maple Grove for diagnostic and therapeutic neural blockade of the lumbar sympathetic nerves suspected of causing her lower extremity pain.

12. On this date, Dr. Thomas G. Cohn performed a lumbar sympathetic block at the L2 level, L3 level, and L4 level on the left side.

13. On this date, the medications administrated were a solution containing 40mg methylprednisolone 80mg/mL mixed with 5mL bupivacaine 0.25%, administered at all three levels (total of 120mg methylprednisolone).

14. On August 10, 2012, Plaintiff presented at MAPS Clinic in Maple Grove for a second lumbar sympathetic nerve block at the L2 level, L3 level, and L4 level on the right side performed by Dr. Thomas G. Cohn.

15. On this date, the medications administrated were a solution containing 40mg methylprednisolone 80mg/mL mixed with 5mL bupivacaine 0.25%, administered at all three levels (total of 120mg methylprednisolone).

16. The methylprednisolone acetate that was injected into Plaintiff was manufactured by NECC.

NECC Compounding Pharmacy and Contamination of Steroid Product

17. NECC is a compounding pharmacy and is in the business of creating pharmaceutical products for individual patients. NECC combines ingredients and applies various processes to create pharmaceutical products.

18. Compounding pharmacies, such as NECC, are licensed and regulated by individual states and not by the United States Food and Drug Administration ("FDA").

19. Compounded drugs are not reviewed by the FDA for quality, safety and efficacy prior to marketing/prescribing and are not manufactured under federal Good Manufacturing Practice regulations, which is a set of standards established through federal regulation to ensure

products meet specific requirements for identity, quality, potency and purity. Thus, there is no formal federal oversight to ensure quality and product integrity.

20. Prior to July 31, 2012, pharmacy-compounded drugs were associated with quality defects, infectious disease outbreaks, and other adverse events.

21. Although at times compounded drugs may be necessary for particular patients, the FDA recommends that FDA-approved products should be used wherever possible to meet a patient's individual needs as compounded drugs lack federal oversight, regulation, and standards for drug approval and safety.

22. The responsibility for recommending compounded drugs rests with the prescribing physician.

23. NECC is not licensed by the State of Massachusetts, the State of Minnesota, or any other state to sell pharmaceutical products in bulk.

24. NECC is only authorized to produce pharmaceuticals for individual, discrete persons with a prescription.

25. Upon information and belief, NECC sold pharmaceuticals in bulk in 2011 and 2012 despite the lack of a license to do so.

26. Selling of pharmaceuticals in bulk without proper FDA authorization is a violation of federal law.

27. Selling of pharmaceuticals in bulk without a license to sell in bulk is a violation of Minnesota law. On October 10, 2012, the Minneapolis Star Tribune quoted Dr. David Schultz, the founder and owner of MAPS, as saying he was unaware of that rule. According to the article, he stated "[t]hat's news to me," and that the New England company was "well respected" and that it had assured him "that they have all the appropriate licenses in place."

28. Methylprednisolone acetate is a drug typically used for its anti-inflammatory effects.

29. One common use of methylprednisolone acetate is to inject it into the epidural space in the lumbar spine to reduce inflammation and resulting pain from herniated and bulging discs.

30. Prior to September 26, 2012, NECC produced and sold discrete lots of methylprednisolone acetate that were adulterated with the fungus *Exserohilum rostratum*, *Aspergillus fumigatus*, and/or other fungi, which are potentially deadly pathogens that can cause illness and death if they are able to enter into the fluid surrounding the brain and spinal cord known as cerebral spinal fluid ("CSF").

31. Upon information and believe, MAPS purchased the contaminated product in bulk from NECC prior to September 26, 2012.

32. On September 26, 2012, NECC voluntarily recalled three lots of preservative-free methylprednisolone acetate that were adulterated with fungus. On October 6, 2012, NECC expanded the recall to include all products in circulation that were distributed from its facility in Framingham, Massachusetts.

33. In October 2012, MAPS worked with the Minnesota Department of Health to identify and notify patients who had received an injection of the contaminated steroid product between May 21 and September 26, 2012.

34. On or about October 8, 2012, Plaintiff received a phone call from the Minnesota Department of Health informing her that she may have received injections with tainted steroids.

35. On or about October 11, 2012, Plaintiff received notice from MAPS that she had been injected with a product that was manufactured by NECC.

Fungal Meningitis Infection and Outbreak

36. Meningitis is a disease caused by the inflammation of the protective membranes covering the brain and spinal cord known as the meninges. The inflammation is typically caused by an infection of the CSF.

37. Meningitis may develop in response to a number of causes, usually bacterial or viral, but meningitis can also be caused by fungal infections.

38. Symptoms of meningitis include new or worsening headache, fever, sensitivity to light, stiff neck, new weakness or numbness in any part of the body, and slurred speech.

39. Meningitis caused by a fungus is called fungal meningitis. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord.

40. Through an epidemiological investigation, the Centers for Disease Control and Prevention ("CDC"), in collaboration with state and local health departments and the FDA, linked a multistate outbreak of fungal infections, including fungal meningitis, to medicines and products manufactured by NECC.

41. Although the investigation is ongoing, as of March 11, 2013, 20 states were included in the outbreak with 722 total CDC-confirmed cases of illness and infection related to the steroids, including 50 deaths.

Medical Treatment and Future Care

42. Plaintiff is a CDC-confirmed case arising from the NECC outbreak.

43. Plaintiff contracted fungal meningitis as a direct result of receiving contaminated steroid injections from MAPS.

44. On or about October 10, 2012, after receiving notification from the Minnesota Department of Health that she may have received the tainted steroid injection, Plaintiff presented at Mercy Hospital in Coon Rapids, Minnesota suffering from a headache.

45. On or about October 10, 2012, Plaintiff underwent a lumbar puncture procedure and had blood samples taken at Mercy Hospital in Coon Rapids, Minnesota.

46. On or about October 11, 2012, Plaintiff underwent a magnetic resonance imaging ("MRI") at Mercy Hospital.

47. On or about October 12, 2012, Plaintiff was contacted by Minnesota Department of Health stating her CSF laboratory results were abnormal. Plaintiff returned and was admitted to Mercy Hospital for treatment.

48. On October 14, 2012, while she was hospitalized, the Minnesota Department of Health confirmed that Plaintiff was positive for fungal meningitis.

49. Plaintiff was hospitalized for approximately ten (10) days, in which she received intravenous anti-fungal medication. Plaintiff suffered from severe hallucinations, extreme pain, flu-like symptoms, blurry vision and dizziness.

50. As a direct and proximate cause of the infection, on October 16, 2012, the silicone spacer that was placed on September 14, 2012, was surgically removed as it was a potential harbor for infection. As a result, Plaintiff is no longer a candidate for future implantation of spinal stimulators for treatment of her CRPS.

51. Following her hospitalization, Plaintiff has continued to take oral anti-fungal medication, treated with an infectious disease physician biweekly, and continued to have weekly bloodwork. Due to Plaintiff's CRPS, she had extensive bruising and pain from the bloodwork.

52. As a result of the fungal meningitis infection caused by receiving a contaminated steroid injection while in the care of MAPS, Plaintiff suffered and will suffer in the future the following injuries and damages:

a. Medical and hospital expenses for the treatment of injuries;

b. Physical and mental pain, disability, and emotional distress;

c. Wage loss and loss of future earning capacity; and

d. Other harms and losses to be proven at trial in an amount greater than Fifty-Thousand dollars ($50,000.00).

COUNT I

GENERAL NEGLIGENCE

53. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and alleges as follows:

54. Defendant MAPS owed a duty to its patients, including Plaintiff, to use reasonable care and attention for the safety of its patients, which included administering products and medications that were safe and not adulterated with potentially harmful pathogens and exercising reasonable care in choosing a drug or medicine to treat its patients. Defendant breached this duty by, among other acts and omissions:

a. purchasing compounded drugs in bulk from NECC, a compounding pharmacy unlicensed to sell in bulk;

b. inadequately investigating, evaluating, screening, auditing, and monitoring NECC to ensure that it was purchasing a quality product including determining where the raw product was obtained and whether it was pharmaceutical grade for humans, how the batch was stored, whether it had been tested for purity, how and when the

product was compounded including sterility, and whether the equipment was free of contaminants;

c. failing to acquire information from NECC as to whether their facility was FDA registered;

55. As a direct and proximate result of Defendant's negligence, Plaintiff sustained damages as set forth in the preceding paragraphs.

COUNT II

BREACH OF IMPLIED WARRANTY

56. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and alleges as follows.

57. The steroids sold by MAPS to Plaintiff would not pass without objection in the trade; were not of fair or average quality within their description, and were not fit for the ordinary purposes for which they were intended.

58. Plaintiff was a foreseeable consumer of the defective product.

59. These actions were a breach of the implied warranty of merchantability and fitness.

60. This breach of warranty was a direct and proximate cause of the Plaintiff's injuries.

61. As a direct result of the breach, Plaintiff suffered harms and losses as described in the preceding paragraphs.

COUNT III

NEGLIGENCE PER SE

62. Plaintiff reasserts and re-alleges each and every matter and thing as set forth in the preceding paragraphs.

63. Defendant MAPS owed a duty to consumers, including Plaintiff, to abide by all applicable laws regarding medications and to use only medications that complied with all applicable federal and state drug laws and regulations.

64. At all times relevant to this action, MAPS failed to comply with Minn. Stat. § 151.46 which provides that it is unlawful for any person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under the laws of the state. Under Minnesota law, only a drug manufacturer or drug wholesaler may sell drugs in bulk. In this case, where MAPS was purchasing steroids in bulk from NECC, which was not licensed in Minnesota as a drug manufacturer or a drug wholesaler, it was in violation of Minnesota law.

65. Under Minnesota law, the fact that Defendant MAPS failed to comply with state law is evidence that it breached its duty of reasonable care and is negligence per se.

66. Plaintiff was in the class of people intended to be protected by drug sale laws.

67. The failure by Defendant MAPS to comply with these laws was a direct and proximate cause of the Plaintiff's injuries.

COUNT IV

FAILURE TO OBTAIN INFORMED CONSENT

68. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and allege as follows:

69. Defendant MAPS had a duty to disclose sufficient information about the proposed treatment to obtain Plaintiff's informed consent, including: the fact that the drugs were purchased in violation of Minnesota law, the risks of death or serious bodily harm which were of significant probability; the risks that a skilled practitioner of good standing in the community would have disclosed; and any risks MAPS knew or should have known would be important to the particular patient.

70. Defendant MAPS breached this duty by, among other acts and omissions, failing to educate Plaintiff on the legality of the steroids and the possible adverse consequences and risks of the steroid injection manufactured by a compounding pharmacy; failing to disclose to Plaintiff that the steroid injection was purchased from a compounding pharmacy, including the risks inherent with drugs produced by such pharmacies; failing to inform Plaintiff that a substantially similar FDA-approved medication could be alternatively available; and failing to disclose that the steroid injection was purchased illegally in bulk from NECC, a compounding pharmacy that was not licensed to sell in bulk.

71. Defendant's breach was a direct and proximate cause of Plaintiff's fungal meningitis infection and the damages as set forth in the preceding paragraphs. Plaintiff, nor any reasonably prudent patient in the Plaintiff's position, would not have consented to the treatment provided by Defendant MAPS if she had been adequately informed.

WHEREFORE, Plaintiff prays judgment against the Defendant in an amount greater than Fifty Thousand Dollars ($50,000.00); for statutory interest on all accrued claims; and for reasonable costs and disbursements incurred in the prosecution of this action.

ACKNOWLEDGMENT

The undersigned hereby acknowledges that sanctions may be imposed pursuant to Minn. Stat. § 549.211, subd. 1.

Dated: March 18, 2013

PritzkerOlsen, P.A.

By: _____

Elliot L. Olsen (#0203750)
Ryan M. Osterholm (#0390152)
Attorneys for Plaintiff
2950 Plaza Seven
45 South 7th Street
Minneapolis, MN 55402-1652
Telephone No. (612) 338-0202

STATE OF MINNESOTA

COUNTY OF HENNEPIN

DISTRICT COURT

FOURTH JUDICIAL DISTRICT

Traci M. Maccoux,

Plaintiff,

v.

Medical Advanced Pain Specialists, P.A.,

Defendant.

Case Type: Product Liability
Court File No.: 27-CV-13-4786
Judge Ronald L. Abrams

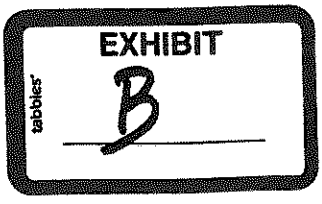
NOTICE OF MOTION AND MOTION TO DISMISS

PLEASE TAKE NOTICE that on the 5th day of June, 2013 before The Honorable Ronald L. Abrams in Hennepin County District Court, Courtroom 1657, City of Minneapolis, Minnesota, Defendant Medical Advanced Pain Specialists, P.A. will bring on for hearing at 1:30 p.m., the following motion:

MOTION TO DISMISS

Defendant Medical Advanced Pain Specialists, P.A. hereby moves for dismissal of Plaintiff's claims in their entirety pursuant to Rule 12 of the Minnesota Rules of Civil Procedure, including Rule 12.02(e) and Rule 12.03. This motion is brought on the grounds that Counts II and III of the Complaint fail to state a claim upon which relief can be granted, and that Defendant is entitled to a judgment of dismissal as a matter of law as to Counts II and III of the Complaint.

This motion will be based on all files, records and proceedings herein including memoranda and other relevant material to be submitted to the Court pursuant to the General Rules of Practice for the District Courts.



Dated: April 08, 2013

Respectfully submitted,

Lind, Jensen, Sullivan & Peterson
A Professional Association

Paul C. Peterson, I.D. No. 151543
William L. Davidson, I.D. No. 201777
Attorneys for Defendant
Medical Advanced Pain Specialists, P.A.
1300 AT&T Tower
901 Marquette Avenue South
Minneapolis, Minnesota 55402
(612) 333-3637

ACKNOWLEDGMENT

The undersigned acknowledges that pursuant to Minn. Stat. § 549.211, the Court may award to any opposing party costs, disbursements and reasonable attorneys' fees and witness fees if the party represented by the undersigned, or the undersigned, acts in bad faith, asserts a claim or defense that is frivolous and costly to the other party, asserts an unfounded position solely to delay the proceedings, or harasses or commits a fraud upon the Court.

William L. Davidson

STATE OF MINNESOTA

COUNTY OF HENNEPIN

DISTRICT COURT

FOURTH JUDICIAL DISTRICT

Traci M. Maccoux,

Plaintiff,

v.

Medical Advanced Pain Specialists, P.A.,

Defendant.

Case Type: Product Liability
Court File No.: 27-CV-13-4786
Judge Ronald L. Abrams

Memorandum of Law in Support of Defendant's Motion for Partial Dismissal

Introduction

Defendant Medical Advanced Pain Specialists, P.A. ("MAPS") moves to dismiss two of the four claims Plaintiff Traci Maccoux has asserted concerning this medical malpractice case. The Court should reject Maccoux' attempt to expand this case beyond the negligence, Count I, and informed consent, Count IV, claims she has asserted. Maccoux' assertion of claims for negligence per se and a breach of an implied warranty are not appropriate under Minnesota law and unnecessarily complicate the allegations of malpractice in this case.

Maccoux' negligence per se claim, Count III, fails because the statute upon which she attempts to assert a claim does not apply to MAPS' conduct, and the Legislature did not approve a private cause of action under the statute. Even if a private cause of action was allowed generally under Chapter 151, which regulates pharmacists and pharmacies, the Legislature expressly created an exception for doctors and clinics authorizing them to prescribe medications without regulatory oversight under Chapter 151. Accordingly,

MAPS did not violate the statute Maccoux references. Maccoux' negligence per se claim fails because MAPS is not liable for the alleged illegal conduct of the pharmacy that prepared the contaminated medication.

Maccoux' breach of implied warranty claim, Count II, fails because MAPS provided professional medical services to Maccoux when it treated her for the chronic pain condition she has had for over a decade. Minnesota does not recognize or permit warranty claims against a medical professional. Instead, Minnesota follows the well-established and long-standing traditional rule that allows malpractice claims against professionals, but does not permit warranty claims against them. Accordingly, Maccoux' warranty claim should be dismissed. Her medical malpractice lawsuit should proceed against MAPS only on the two other counts in the Complaint, a claim for general negligence, Count I, and a claim for an alleged failure to obtain informed consent, Count III. While MAPS does not agree that it breached its standard of care to Maccoux or failed to obtain her informed consent, MAPS recognizes Maccoux has stated claims under these two counts that are not subject to dismissal under Rule 12.

Factual and procedural background

This lawsuit arises out of a contaminated steroid medication that the New England Compounding Center ("NECC"), a Massachusetts pharmacy, produced. Complaint, ¶ 4. NECC is not a party to this lawsuit, and Maccoux has not sued it. Instead, Maccoux has sued MAPS, a clinic where she sought medical treatment for a chronic pain condition in her legs and arms. *Id.*, ¶ 10.

Maccoux claims she contracted fungal meningitis from two lumbar sympathetic nerve blocks performed at MAPS in late July and early August, 2012, to address pain complaints on her left and right side respectively. *Id.*, ¶¶11-14, 43. During both visits for treatment, Dr. Thomas Cohn administered, through injections, a methylprednisolone acetate mixture that NECC produced. *Id.*, ¶¶ 4, 13, 15-16. Methylprednisolone acetate is an anti-inflammatory drug that is commonly injected into the epidural space of the lumbar spine to reduce inflammation and pain. *Id.*, ¶¶ 28-29. Maccoux alleges the methylprednisolone acetate NECC produced was adulterated with fungus, and notes MAPS purchased this product from NECC. *Id.*, ¶¶ 30, 31. Maccoux claims she contracted fungal meningitis as a result of the steroid injections she received from MAPS. *Id.*, ¶ 43.

Maccoux has asserted four counts in her Complaint against MAPS. Count I asserts a standard medical malpractice claim – a claim for "general negligence" – and Maccoux asserts MAPS breached its duty of care to her in administering an adulterated drug. *Id.*, ¶ 54. Count IV asserts another medical malpractice claim and alleges MAPS failed to obtain Maccoux' informed consent regarding the steroid injections administered to her. Complaint, ¶¶ 69-71.

Specifically, Maccoux claims MAPS was negligent in: (1) purchasing compounded drugs in bulk from NECC, which Maccoux claims NECC was not licensed to sell; (2) not ensuring it was purchasing a quality product and failing to investigate, audit, and monitor NECC to ensure NECC produced a quality product; and (3) failing to obtain information from NECC to determine whether it was registered with the Food and Drug Administration ("FDA"). *Id*, ¶ 54(a) – (c). NECC has held a Non-Resident Pharmacy

License with the Minnesota Board of Pharmacy since 2003, and remains licensed in Minnesota.[1] *See* https://www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx (under "General Services," click on "Verify License or Registration," and do a licensee search for "New England Compounding Center" or license number "262288"); Davidson Aff., Ex. 1.

In Count II, Maccoux claims MAPS breached an implied warranty of merchantability and fitness in selling the steroids administered to her as part of her medical treatment for her chronic pain. *Id.*, ¶¶ 57-61.

Count III asserts a negligence per se claim. *Id.*, ¶¶ 63-67. Maccoux contends MAPS failed to comply with Minnesota Statute § 151.46, and she asserts this statute makes it unlawful for any person to knowingly purchase or receive a prescription drug from an unlicensed person or entity. *Id.*, ¶ 64. Maccoux asserts NECC was not permitted to sell drugs in bulk and therefore MAPS' purchase of steroids from NECC violated Minnesota law. *Id.*

---

[1] The Legislature mandates that nonresident pharmacies "shall be" registered by the Minnesota Board of Pharmacy "upon the disclosure and certification by a pharmacy" that it: (1) is licensed in the state where its dispensing facility is located and from which the drugs are dispensed; (2) provides information regarding the corporate officers and all pharmacists involved in dispensing drugs to Minnesota residents; (3) complies with all lawful directives and information requests from the Board of Pharmacy of all states where the pharmacy is licensed or registered; (4) maintains records of drugs dispensed to Minnesota residents; (5) cooperates with the Minnesota Board of Pharmacy; (6) makes available a toll-free number to Minnesota patients to facilitate communication by Minnesota patients; and, (7) dispense medications in unit-dose packaging for residents of long-term care facilities in Minnesota or otherwise comply with the statute regulating pharmacy interaction with long-term care facilities. Minn. Stat. § 151.19, subd. 2. Similarly, the Minnesota Board of Pharmacy has the discretion to "grant licensure without examination to any pharmacist licensed by . . . a similar board [of pharmacy] of another state which accords similar recognition to licensees of this state; provided the requirements for licensure in such other state are in the opinion of the board equivalent to those herein provided." Minn. Stat. § 151.12 (recognizing reciprocal licensure).

Standard for a Rule 12 motion to dismiss

Rule 12.02(e) of the Minnesota Rules of Civil Procedure provides for the dismissal of a claim if a complaint fails "to state a claim upon which relief can be granted." The Court reviews the pleadings to determine whether relief can be granted to a plaintiff, even assuming all of the plaintiff's allegations are assumed to be true. A motion to dismiss under Rule 12.02(e) is the proper means to determine whether a cause of action is recognized. *Nelson v. Productive Alternatives, Inc.*, 715 N.W.2d 452, 454 (Minn. 2006); *Johnson v. Peterson*, 734 N.W.2d 275, 277-78 (Minn. App. 2007) (affirming dismissal of negligent training and hiring claims because Minnesota does not recognize such cause of actions).

Similarly, Rule 12.03 provides that "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." A complaint must set forth a legally sufficient claim for relief to survive. *Williams v. Bd. of Regents of Univ. of Minnesota*, 763 N.W.2d 646, 651 (Minn. App. 2009). If the pleadings create no fact issues, a motion for judgment on the pleadings should be granted. *Ryan v. Lodermeier*, 387 N.W.2d 652, 653 (Minn. App. 1986). Thus, if there are no contested facts to be proved, the Court may draw legal conclusions from the facts on a motion for judgment on the pleadings. *Nationwide Corp. v. Nw. Nat. Life Ins. Co.*, 251 Minn. 255, 268, 87 N.W.2d 671, 681 (1958).

The Court may assume the facts alleged in the complaint are true when considering a Rule 12.03 motion. *Lorix v. Crompton Corp.*, 736 N.W.2d 619, 623 (Minn. 2007). In evaluating the motion, the Court may consider the pleadings, as well as

documents that are incorporated by reference into the pleadings. *Stephenson v. Plastics Corp. of Am.*, 276 Minn. 400, 402, 150 N.W.2d 668, 671, n. 1 (1967); *Marchant Inv. & Mgmt. Co., Inc. v. St. Anthony W. Neighborhood Org., Inc.*, 694 N.W.2d 92, 95 (Minn. App. 2005).

Argument and Authorities

I. Maccoux' Count III asserting a negligence per se claim against MAPS should be dismissed because the statute relied upon, Minnesota Statute § 151.46, does not provide a private cause of action, and the statute's regulation of pharmacies and pharmacists does not apply to MAPS.

In addition to the negligence claim she has asserted in Count I of her Complaint, Maccoux contends MAPS failed to comply with a statute – Minnesota Statute § 151.46 – and the supposed failure to comply with this law is negligence per se. Complaint, Count III (¶¶ 63-67).

Maccoux has failed to state a claim upon which relief can be granted as to her negligence per se claim. This claim fails for several reasons. First, the statute does not apply to MAPS' conduct. Second, the statute does not create a private cause of action. Finally, the Legislature created an express exception for those licensed to practice medicine from the requirements of Chapter 151. Accordingly, the statute does not apply to MAPS, and it cannot be liable to Maccoux for the alleged statutory violation.

Negligence per se is a form of ordinary negligence where liability potentially results if a statute is violated. *Seim v. Garavalia*, 306 N.W.2d 806, 810 (Minn. 1981). It, however, "is not liability per se." *Id.* A "violation of a statute does not constitute negligence per se unless the victim of the harm was intended to be protected by the statute and unless the harm suffered is of the kind intended to be prevented by the statute." *Anderson v. Anoka Henn. Sch. Dist. 11*, 678 N.W.2d 651, 662-63 (Minn. 2004)

(rejecting argument that OSHA violation was negligence per se involving student injured in a woodworking class; OSHA standard applied to workplaces for protection of employees and not to schools for protection of students). Because the statute Maccoux relies upon regulates pharmacists and pharmacies, it does not support a negligence per se claim against MAPS, a medical clinic, for its treatment of Maccoux.

Additionally, if a statute is designed to protect the public at large, rather than a particular class of individuals, the statute does not set the standard of care, and negligence per se does not exist. *Kronzer v. First Nat. Bank of Mpls.*, 305 Minn. 415, 235 N.W.2d 187, 193 (1975). As noted below, the statute Maccoux relies upon does not apply to MAPS and exists generally to protect the public at large instead of a particular class of individuals. Accordingly, Maccoux' negligence per se claim should be dismissed, and she should proceed with her traditional malpractice claims. *See In re Shigellosis Litigation*, 647 N.W.2d 1, 10-11 (Minn. App. 2002) (affirming trial court's decision to not grant JNOV to defendant restaurant that tried to assert negligence per se claim against importer that sold parsley contaminated with bacteria; federal statute prohibiting the introduction of adulterated food into interstate commerce did not give "rise to a civil action" or support a negligence per se claim).

A. The statute Maccoux relies upon does not apply to MAPS, and there is no private cause of action for an alleged violation of the statute.

Maccoux contends Minnesota Statute § 151.46 was violated. The statute Maccoux references does not apply to MAPS and does not create a private cause of action or remedy for an alleged violation of the statute. Minnesota Statute § 151.46 regulates the conduct of pharmacists and pharmacies, and not medical doctors and clinics.

Section 151.46 is part of the Wholesale Drug Distribution Licensing Act of 1990 ("Distribution Licensing Act"). The Distribution Licensing Act encompasses Minnesota Statutes §§ 151.42-.51. It is included in Chapter 151, which regulates pharmacies generally. The scope of the Distribution Licensing Act applies "to any person, partnership, corporation, or business firm engaging in the wholesale distribution of prescription drugs within the state." Minn. Stat. § 151.43. MAPS' use and prescription of medications in treating patients does not fall within the definition of the "wholesale distribution of prescription drugs." Because MAPS' treatment of patients is not regulated under the Distribution Licensing Act, Maccoux cannot pursue a claim against MAPS under the Act.

"[W]holesale drug distribution" regulated under the Distribution Licensing Act is defined to mean, in relevant part, "distribution of prescription or non-prescription drugs to persons *other than a consumer or patient*[.]" Minn. Stat. § 151.44(a) (emphasis added).[2] In other words, the Distribution Licensing Act does *not* apply to a doctor or clinic prescribing drugs to "a consumer or patient." *Id.* Thus, the Distribution Licensing Act is not applicable to MAPS' treatment of Maccoux.

In addition, the Legislature did not create or authorize a private cause of action when it enacted the Distribution Licensing Act. A statute does not give rise to a civil cause of action unless the language of the statute is explicit, or if such a civil cause of action can be determined by clear implication. *Larson v. Dunn*, 460 N.W.2d 39, 47 n.4 (Minn. 1990). Maccoux can point to nothing in the Distribution Licensing Act, or in Chapter 151 for that matter, authorizing a private cause of action against MAPS for an

[2] Section 151.44(a) sets out nine exceptions to the definition of a "wholesale drug distribution." The exceptions are not applicable to this case.

alleged violation of Section 151.46. Instead, the Legislature generally determined that violations of Chapter 151 ordinarily would subject a violator to a misdemeanor. *See* Minn. Stat. § 151.29. As to Section 151.46 specifically, the Legislature expressly stated that a "person violating the provision of this section is guilty of a misdemeanor." *Id.* MAPS did not violate Section 151.46. As noted, its use and prescription of drugs to treat Maccoux as a patient does not subject it to regulation under the Distribution Licensing Act.

Because there is no explicit language creating a private cause of action, and one does not exist by clear implication, this Court should reject any attempt from Maccoux to create one. "Principles of judicial restraint preclude [a court] from creating a new statutory cause of action that does not exist at common law where the legislature has not either by the statute's express terms or by implication provided for civil tort liability." *Bruegger v. Faribault County Sheriff's Dep't*, 497 N.W.2d 260, 262 (Minn. 1993) (holding that the Crime Victims Reparations Act does not create a private cause of action against law enforcement agencies that fail to inform crime victims of their right to seek reparations); *see also Becker v. Mayo Foundation*, 737 N.W.2d 200, 207-09 (Minn. 2007) (affirming dismissal of claim attempting to recover under the Child Abuse Reporting Act; no private cause of action created explicitly and no such action impliedly created when Legislature chose to impose only criminal penalties for violations of the Act).

Moreover, had the Legislature intended to create a private cause of action for a violation of the Distribution Licensing Act, it could have done so. Because it did not, this Court should not create or permit such a claim. Whether a statute creates a private cause of action is a question of legislative intent. *Touche Ross & Co. v. Redington*, 442 U.S. 560,

571 (1979); *Morris v. Am. Fam. Mut. Ins. Co.*, 386 N.W.2d 233, 236-38 (Minn. 1986) (holding that no cause of action for a violation of Minnesota's Unfair Claims Practices Act exists against an insurance company).

Significantly, the Legislature knows how to create a private cause of action when it wishes to do so. Indeed, elsewhere in Chapter 151 it expressly authorized a cause of action for certain conduct. *See* Minn. Stat. § 151.061, subd. 2 (authorizing "a civil action [to] recover damages" along with costs and fees for "[a]ny person injured by unfair discrimination" in pricing of prescription drugs distributed at wholesale but not retail). By expressly creating a private cause of action for cases of unfair price discrimination, but not a cause of action under the Distribution Licensing Act, the Legislature made its intent clear. "[I]t is an elemental canon of statutory construction that where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it." *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11, 19 (1979); *Touche Ross*, 442 U.S. at 572-74 (recognizing a private cause of action authorized in another part of the statutory scheme supports the conclusion that no private cause of action is authorized under another part of the statute).

Given the language of the statute, and the reluctance of courts to extend the law and create new causes of action, this Court should dismiss Count III. *See D.A.B. v. Brown*, 570 N.W.2d 168, 170-72 (Minn. App. 1997) (affirming dismissal of breach of fiduciary duty claim against a physician based upon purported violation of Minnesota Statute § 147.091, which prohibits physicians from receiving compensation for the referral of patients or the prescribing of drugs, because the "statute does not provide a private remedy," and noting

it was not appropriate to create a new cause of action; "despite counsel's creative characterizations and foreign support, this case is a malpractice action"); *see also State v. Red Owl Stores,* 262 Minn. 31, 115 N.W.2d 643, 659 (1962) (noting it "is for the legislature and not the courts to establish policies and standards with reference to the sale of drugs and medicines"). Count III fails as a matter of law because the Distribution Licensing Act does not apply to MAPS, and because the Legislature did not create a private cause of action for any alleged violations of Section 151.46.

B. Even assuming the Distribution Licensing Act might apply and an action could exist for an alleged violation of Section 151.46, Maccoux' attempted claim against MAPS fails as a matter of law because an express statutory exception applies to the use and prescription of medicine in treating Maccoux.

As noted, the Distribution Licensing Act does not apply to MAPS because the definition of "wholesale drug distribution" does not include the distribution of drugs to "a consumer or patient." Minn. Stat. § 151.44(a). Even if the Distribution Licensing Act was somehow construed to apply to MAPS generally, Maccoux still has no statutory claim against MAPS. In addition to excluding the prescription of drugs to patients from the definition of "wholesale drug distribution," the Legislature elsewhere also expressly authorized doctors and clinics to prescribe drugs and exempted them from regulation under Chapter 151. This exemption exists for good reason. Doctors and clinics are subject to separate statutory oversight from other licensing boards and entities. As well, they remain subject to potential malpractice claims if they deviated from the standard of care. They are not, however, subject to liability for an alleged violation of Section 151.46.

Instead, the Legislature recognized pharmacists are the ones responsible for the quality of drugs and medicines they dispense.[3] Thus, Count III should be dismissed.

Minnesota Statute § 151.26, subd. 1 provides a broad exception to those licensed to practice medicine from inspection or oversight under Chapter 151. Section 151.26, captioned as "Exceptions," provides in relevant part that doctors are permitted to administer and furnish drugs and medicines to their patients for treatment:

> **Nothing in this chapter shall subject a person duly licensed in this state to practice medicine . . . to inspection** by the State Board of Pharmacy, **nor prevent the person from administering drugs, medicines,** chemicals, or poisons **in the person's practice, nor prevent a duly licensed practitioner from furnishing to a patient properly packaged and labeled drugs, medicines,** chemicals, or poisons **as may be considered appropriate in the treatment of such patient**; unless the person is engaged in the dispensing, sale, or distribution of drugs and the board provides reasonable notice of an inspection.

Id. (emphasis added). This legislative exception further provides that physicians are permitted to use drugs and medicines in their practice, and that nothing in Chapter 151 "shall prevent the sale of drugs [or] medicines . . . to licensed physicians for use in their practice[.]" *Id.* Given the unambiguous statutory exception that exempts doctors from oversight under Chapter 151 if they use and prescribe drugs and medicine in the treatment of patients, Maccoux' Count III fails to state a claim upon which relief can be granted. Accordingly, this Court should dismiss Count III.

---

[3] Minnesota Statute § 151.22 directly addresses "Liability for quality of drugs" and states pharmacists are responsible for the quality of drugs and medicines:

> Every pharmacist in charge or proprietor of a pharmacy shall be responsible for the quality of all drugs, medicines chemicals, and poisons procured for use and sold therein, except proprietary medicines or other articles sold in the original package of the manufacturer.

III. Maccoux' Count II, which attempts to assert a breach of an implied warranty claim against MAPS, should be dismissed because Minnesota does not recognize a warranty claim against a medical professional.

This Court should reject Maccoux' attempt to expand the law and create a new warranty cause of action against medical providers that has not been recognized in Minnesota. Minnesota courts specifically reject attempts to pursue warranty claims against professionals. Importantly, the Minnesota Supreme Court has specifically stated that warranty claims are not appropriate against medical and other professionals. Accordingly, it is appropriate to dismiss Maccoux' breach of an implied warranty claim, and instead let her pursue the traditional claims of medical malpractice she has asserted.

In *City of Mounds View v. Walijarvi*, 263 N.W.2d 420 (Minn. 1978), the Court addressed the city's claims arising out of water seepage and damage to an addition to city hall the architects designed. The city sued the architects for negligence as well as for breach of warranties, including a claim for breach of implied warranties. *Id.* at 421. The district court dismissed the warranty claims, which the Supreme Court affirmed. *Id.*

In rejecting the warranty claims, the Supreme Court expressly noted Minnesota follows the well-established and long-standing majority rule that professionals may be subject to claims of negligence, but they are not responsible for warranting the result of their efforts. *Id.* at 423-24. The Court directly explained its reasoning and the rationale for this "general rule" that applies to architects as well as "other vendors of professional services." *Id.* at 424 (noting the reasoning is "relatively straightforward"). The Court stated that while professionals could be subjected to suits for negligence and held responsible for a standard of care as those of other similarly situated professionals, they

cannot be expected to produce perfect results and are not liable under a warranty theory of liability:

> Architects, **doctors,** engineers, attorneys, and others deal in somewhat inexact sciences and are continually called upon to exercise their skilled judgment in order to anticipate and provide for random factors which are incapable of precise measurement. The indeterminate nature of these factors makes it impossible for professional service people to gauge them with complete accuracy in every instance. **Thus, doctors cannot promise that every operation will be successful**; a lawyer can never be certain that a contract he drafts is without latent ambiguity; and an architect cannot be certain that a structural design will interact with natural forces as anticipated. **Because of the inescapable possibility of error which inheres in these services, the law has traditionally required, not perfect results, but rather the exercise of that skill and judgment which can be reasonably expected from similarly situated professionals.**

Id. (emphasis added). After carefully reexamining the "subject of professional services" and potential warranty claims against professionals, the Court held that such claims were not appropriate. *Id.* (stating "[we] are not persuaded that the time has yet arrived for the abrogation of the traditional rule" prohibiting warranty claims against professionals).

Importantly, the Supreme Court did not limit its concerns or reasoning to just architects. The Court specifically stated warranty claims against professionals are not appropriate, while noting standard malpractice actions are permitted. *Id.* at 425 (stating "we decline to extend the implied warranty/strict liability doctrine to cover vendors of professional services").

Another Minnesota Supreme Court decision that rejected a warranty claim also controls. In *Balkowitsch v. Minneapolis War Memorial Blood Bank, Inc.*, 270 Minn. 151, 132 N.W.2d 805 (1965), the Minnesota Supreme Court expressly rejected a breach of implied warranty claim a patient asserted alleging she contracted serum hepatitis from a blood

transfusion. *Balkowitsch* carefully examined and rejected plaintiff's argument and theory that the transfusion was a sale of a product for which a warranty applied. *Id.*, 132 N.W.2d at 809-10 ("it is apparent that courts have rejected the sales analogy by which liability in blood-transfusion cases might be imposed on the theory of implied warranty. We agree with those courts which hold that the furnishing of blood is more in the nature of a service than in the sale of goods").[4]

Given these clear pronouncements, and because it is not the function of district courts to establish new causes of action, *see Stubbs v. N. Mem'l Med. Ctr.*, 448 N.W.2d 78, 81 (Minn. App. 1989); *Tereault v. Palmer*, 413 N.W.2d 283, 286 (Minn. App. 1987) ("task of extending existing law falls to the supreme court or the legislature, but it does not fall to [the court of appeals]"), this Court should dismiss Count II and reject Maccoux' implied warranty claim.

---

[4] In rejecting warranty claims against medical professionals, Minnesota is in accord with decisions from numerous jurisdictions that dismiss those claims because medical treatment is a service and not a sale of goods subject to a warranty. "Concepts of purchase and sale cannot separately be attached to the healing materials – such as medicines, drugs or, indeed blood – supplied by the hospital for a price as part of the medical services it offers." *See Perlmutter v. Beth David Hosp.*, 308 N.Y. 100, 123 N.E.2d 792 (1954) (dismissing, for failure to state a claim, an attempted breach of implied warranty claim against a hospital for injuries allegedly resulting from the transfusion of contaminated blood); *see also Magner v. Beth Israel Hosp.*, 120 N.J.Super. 529, 295 A.2d 363 (1972) (agreeing that dismissal of breach of warranty claims against a plastic surgeon and hospital was proper; "[breach of warranty and strict liability] doctrines may be applicable in commercial transactions but not to the medical or dental professions"); *In re Breast Implant Prod. Liab. Litig.*, 503 S.E.2d 445, 449 (S.C. 1998) (dismissing warranty claims against healthcare providers involved in breast implant surgeries because healthcare providers offer services, and not products).

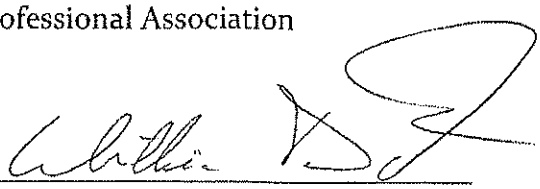
Conclusion

This Court should grant MAPS' motion for partial dismissal. Maccoux' negligence per se and implied warranty claims fail as a matter of law. The statute Maccoux relies upon does not apply to MAPS and does not authorize a private cause of action. Moreover, the Legislature has made clear that the regulations in Chapter 151 do not apply to licensed physicians who use and prescribe drugs and medicines for their patients for treatment. Finally, Minnesota does not permit warranty claims against medical professionals for their treatment of patients. Instead, Minnesota permits malpractice claims against those professionals. Accordingly, this Court should dismiss Counts II and III of the Complaint.

Dated: April 08, 2013

Respectfully submitted,

Lind, Jensen, Sullivan & Peterson
A Professional Association



Paul C. Peterson, I.D. No. 151543
William L. Davidson, I.D. No. 201777
Attorneys for Defendant
Medical Advanced Pain Specialists, P.A.
1300 AT&T Tower
901 Marquette Avenue South
Minneapolis, Minnesota 55402
(612) 333-3637